EXHBIT 5

U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

March 12, 2004

Calories Count
Report of the Working Group on Obesity

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Memorandum of Transmittal

Date February 11, 2004

From Chair and Vice Chair, Obesity Working Group

Subject Working Group Report and Recommendations

To Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

We are pleased to transmit the final report and recommendations of the Food and Drug Administration's (FDA) Obesity Working Group (OWG). You established the OWG on August

11, 2003. The OWG met eight times from August 28, 2003, to January 22, 2004. In addition, the OWG held one public meeting, one workshop, two roundtable discussions (one with health professionals/academicians, and one with representatives of consumer groups), and solicited comments on obesity-related issues. The public meeting examined FDA's role and responsibilities in addressing the major health problem of obesity, focused on issues related to promoting better consumer dietary and lifestyle choices that have the potential to significantly improve the health and well-being of Americans, and obtained stakeholder views on how best to build a framework for messages to consumers about reducing obesity and achieving better nutrition. The science-based public workshop, which was co-sponsored and funded by the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, collected data relevant to FDA efforts to help consumer make better-informed weight management decisions. In addition, some members of the OWG met with representatives from various sectors of the packaged food and restaurant industries.

To accomplish its work, the OWG organized several subgroups (i.e., messages, education, food label, restaurants/industry, therapeutics, research, and stakeholder investment), each designed to focus on a particular aspect of the original charge to prepare a report that outlines an action plan to cover critical dimensions of the obesity problem from FDA's perspective and authorities. In addition, in order to inform its work, the OWG created a knowledge base subgroup. All the subgroups, in turn, met separately and developed respective analyses and recommendations, which serve as the basis for this report.

The report that follows provides, for your consideration, a range of short- and long-term recommendations that are responsive to the charge. The OWG believes that, if the report's recommendations are implemented, they will make a worthy contribution to confronting our Nation's obesity epidemic and helping consumers lead healthier lives through better nutrition. The report also contains a number of appendices, including your original charge memo, the list of OWG members and subgroups, and other supporting material.

We appreciate the opportunity to have served FDA as leaders of the OWG, and we stand ready to facilitate the implementation of the OWG's recommendations.

Lester M. Crawford, D.V.M., Ph.D.
Chair
Deputy Commissioner of
Food and Drugs

Robert E. Brackett, Ph.D.
Vice Chair
Director
Center for Food Safety and
Applied Nutrition

Executive Summary

Obesity is a pervasive public health problem in the United States. Since the late 1980s, adult obesity has steadily and substantially increased in the United States. Today, 64 percent of all

Americans are overweight and over 30 percent are obese; in 1988 through 1992, fewer than 56 percent were overweight and fewer than 23 percent of American adults were obese. The trends for children are even more worrisome. Recent research by the U.S. Centers for Disease Control and Prevention[1] (CDC) shows that 15 percent of children and adolescents aged 6 to 19 are overweight -double the rate of two decades ago (CDC, 2003). As Americans get heavier, their health suffers. Overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers. According to some estimates, at least 400,000 deaths each year may be attributed to obesity (Mokdad, *et al.*, 2004).

To help confront the problem of obesity in the United States and to help consumers lead healthier lives through better nutrition, on August 11, 2003, Mark B. McClellan, M.D., Ph.D., Commissioner of Food and Drugs, created the Food and Drug Administration's (FDA) Obesity Working Group (OWG). He charged the OWG to prepare a report that outlines an action plan to cover critical dimensions of the obesity problem from FDA's perspective and authorities.

This report reflects the work of the OWG to meet the Commissioner's charge and is organized largely around the specific elements of the August 11, 2003, charge.

The problem of obesity has no single cause. Rather, it is the result of numerous factors acting together over time. Similarly, there will be no single solution; obesity will be brought under control only as a result of numerous coordinated, complementary efforts from a variety of sectors of society. Nor can this problem be solved quickly. Any long-lasting reversal of this phenomenon will itself be a long-term process.

The OWG's recommendations are centered on the scientific fact that weight control is primarily a function of balance of the calories eaten and calories expended on physical and metabolic activity (see Appendix B Text Boxes in the report for a fuller discussion). The recommendations contained in this report therefore focus on a "calories count" emphasis for FDA actions. The box on the next page contains the OWG's principal recommendations. The body of this report details the underlying rationale for each of these principal recommendations and additional recommendations. Taken together, they represent a plan of action, founded on science, FDA's public health mission and legal authorities, and the importance of considering consumer and other stakeholder views and needs in addressing obesity.

OWG Principal Recommended Action Items

Food Labeling

- **Calories:** Issue an advance notice of proposed rulemaking (ANPRM) to solicit public comment on how to give more prominence to calories on the food label. As examples, increasing the font size for calories, including a percent Daily Value (%DV) column for total calories, and eliminating the listing for calories from fat.
- **Serving Sizes:** Encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes and label as a single-serving those food packages where the entire content of the package can reasonably be consumed at a single-eating occasion. For example, a 20 oz bottle of soda that currently states 110 calories per serving

and 2.5 servings per bottle could be labeled as containing 275 calories per bottle.

- **Carbohydrates:** File petitions and publish a proposed rule during summer 2004 to provide for nutrient content claims related to carbohydrate content of foods, including guidance for use of the term "net" in relation to the carbohydrate content of foods.
- **Comparative Labeling Statements:** Encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions, including calories (e.g., "instead of cherry pie, try our delicious low fat cherry yogurt - 29 percent fewer calories and 86 percent less fat").

Enforcement Activities

- Together with the Federal Trade Commission (FTC), increase enforcement against weight loss products having false or misleading claims.
- Consider enforcement action against products that declare inaccurate serving sizes.

Educational Partnerships

- As part of a larger DHHS effort, establish relationships with, among others, youth-oriented organizations such as the Girl Scouts of the USA, the National Association of State Universities and Land Grant Colleges (4-H program), to educate Americans about obesity and leading healthier lives through better nutrition.

Restaurants

- Urge the restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for consumers.

Therapeutics

- Convene a meeting of a standing FDA advisory committee meeting to address challenges, as well as gaps in knowledge, about existing drug therapies for the treatment of obesity.
- Revise 1996 draft guidance on developing obesity drugs and re-issue for comment.

Research

- Support and collaborate, as appropriate, on obesity-related research with others, including NIH.
- Pursue research on obesity prevention with U.S.Department of Agriculture/Agricultural Research Service (USDA/ARS).

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(1) See Appendix A for a list of acronyms and abbreviations used throughout this report.

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U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

March 12, 2004

Counting Calories
Report of the Working Group on Obesity

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I. Introduction

A. Public Health Impetus

The nation is currently facing a major long-term public health crisis. In recent years, unprecedented numbers of Americans of all ages have become either overweight or obese.(2) This trend toward overweight and obesity has accelerated during the past decade and is well documented (see Box 1) by numerous scientific analyses. (For convenience, future use in this document of the term obesity includes both overweight and obesity.) Unfortunately, this trend towards obesity shows no signs of abating. If it is not reversed, the gains in life expectancy and quality of life resulting from modern medicine's advances on disease will erode, and more health-related costs will burden the nation's healthcare systems. For these reasons, the trend toward obesity must be reversed.

Box 1 - Facts and Figures on Overweight and Obesity

The scope of the growing and urgent public health problem of obesity is outlined in the Surgeon General's Call to Action (DHHS, 2001). In 1999-2000, 64% of U.S. adults were overweight, increased from 56% when surveyed in 1988-1994; 30% of adults were obese, increased from 23% in the earlier survey (DHHS, 2003; Flegal *et al.*, 2002). Among children age 6 through 19 years, 15% were overweight, compared with 10 to 11% in the earlier survey (CDC, 2003; Ogden *et al.*, 2002). Overweight and obesity are associated with increased morbidity and mortality. It is estimated that about 400,000 deaths per year may be attributed to obesity, and overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers (Mokdad, *et al.*, 2004). The total economic cost of obesity in the United States is up to $117 billion per year (DHHS, 2003), including more than $50 billion in avoidable medical costs, more than 5 percent of total annual health care expenditures (DHHS, 2001; DHHS, 2003).

The prevalence of overweight and obesity varies by gender, age, socioeconomic status, and race and ethnicity (DHHS, 2001). For example, although overweight has increased among all children, the prevalence of overweight and obesity is significantly higher among non-Hispanic black and Mexican-American adolescents than among non-Hispanic white teens (12-19 years old) (Ogden *et al.*, 2002). A majority of non-Hispanic black women over 40 are overweight or obese (Flegal *et al.*, 2002).

The problem of obesity in America has no single cause. Rather, obesity is the result of multiple factors acting together over time, including genetic (Loos and Bouchard, 2003) and environmental factors (Hill and Peters, 1998; Hill *et al.*, 2003).[3] Similarly, there will be no single solution to the problem of obesity; it will be brought under control only as a result of coordinated, complementary efforts from a variety of sectors of society. The obesity epidemic also will not be solved quickly. Any long-lasting reversal of this phenomenon will itself be a long-term process.

Obesity is associated with significant health problems in the pediatric age group and is an important risk factor associated with adult morbidity and mortality. The causes and mitigation of childhood obesity have been and continue to be the focus of much attention (Hill and Trowbridge, 1998; Barlow and Dietz, 1998; Ashton, 2004; Bowman, *et al.*, 2004). A policy statement of the American Academy of Pediatrics proposes strategies for early identification of excessive weight gain by using BMI,[4] for dietary and physical activity interventions during health supervision encounters, and for advocacy and research (AAP, 2003). According to Ritchey and Olson (1983), parental behavior is a dominant influence on children's eating habits. For adults, the literature discusses how having a specific behavior goal for the prevention of weight gain (e.g., increasing physical activity or eating less at each meal) may be key to arresting the obesity epidemic (Wyatt and Hill, 2002; Hill, 2004). In similar fashion, the *Dietary Guidelines for Americans* includes a chapter on physical activity, linking physical activity with nutrition.

The combined efforts of Federal, state and local governments, the packaged food industry, the restaurant industry (including both quickservice and other types of restaurants), the professional health community (including primary care physicians, nutritionists, dietitians, and others), consumer advocacy groups, schools, the media and, of course, committed individuals will all be required to contribute to the solution to the problem of obesity.

The current crisis has been recognized by many of these groups, including a number of our stakeholders, for some time, and many wide-ranging efforts to address and reverse the trends that lead to obesity are already underway. Within the DHHS, Secretary Tommy G. Thompson has led efforts to address the public health problem of obesity. On July 30, 2003, Secretary Thompson convened a roundtable on obesity/nutrition involving experts from academia, the health professions, industry, and government to consider the role that the Department can play in reducing or reversing the weight gain that leads to obesity (see Appendix C for the five questions presented at the roundtable). DHHS also established a Docket in FDA (Docket No. 2003N-0338)

to gather additional information on this topic.

Each group now working on the problem of obesity brings unique resources and expertise to bear on it. Among the major Federal government entities with a responsibility and a capability to address the problem, FDA, within the broader context of DHHS, is bringing its own unique strengths to bear, including relevant legal authorities.

B. FDA Obesity Working Group

In a memorandum dated August 11, 2003 (see Appendix D for the August 11 memorandum), Commissioner of Food and Drugs Mark B. McClellan, M.D., Ph.D., created the OWG and gave it its charge. FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D., chairs the OWG; the Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), Robert E. Brackett, Ph.D., is the vice-chair.[5] Other members of the OWG (see Appendix E for list of OWG members) were selected from across FDA to provide expertise and knowledge in a range of relevant scientific and other disciplines. The Commissioner requested that the OWG deliver, in six months, a report that outlines an action plan covering critical dimensions of the obesity problem as outlined in the charge and to help consumers lead healthier lives through better nutrition.

During its tenure, the OWG met eight times; received briefings from several invited experts from other government agencies; held one public meeting, one workshop, two roundtable discussions (one with health professionals/academicians, and one with representatives of consumer groups); and solicited comments on obesity-related issues, directing them to the Docket that DHHS established in July 2003 (Docket No. 2003N-0338). In addition, some members of the OWG met with representatives from various sectors of the packaged food and restaurant industries.

To accomplish its work, the OWG organized several subgroups (see Appendix F for list of OWG subgroups), each designed to focus on a particular aspect of the Commissioner's original charge. In addition, in order to inform its work, the OWG created a knowledge base subgroup. All the subgroups, in turn, met separately and developed respective analyses and recommendations, which serve as the basis for this report. This report presents the OWG's recommendations that are responsive to the Commissioner's charge, and that the OWG believes can contribute to confronting obesity in the United States.

II. Foundations of this Report

Any FDA effort to address obesity must be based on the following: (a) adherence to fundamental scientific principles; (b) conformance with FDA's public health mission and legal authorities; and (c) consideration of consumer and other stakeholder views and needs.

A. Scientific Principles

Fundamentally, obesity represents an imbalance between energy intake (e.g., caloric intake) and energy output (expended both as physical activity and metabolic activity; see text box on Calorie (Energy) Balance at Appendix B). Although there is much discussion about (1) the

appropriate makeup of the diet in terms of relative proportions of macronutrients (fats [lipids], carbohydrates, and protein) that provide calories and (2) the foods that provide these macronutrients, for maintenance of a healthy body weight it is the consumption and expenditure of calories that is most important. In other words, "calories count."[6]

1. Calories

Quite simply, the OWG's recommendations center on the scientific fact that weight control requires caloric balance. Food supplies the energy that provides fuel for the body and for rebuilding the "wear and tear" one is subjected to during the day. The traditional unit for expressing the energy value of foods is the *kilocalorie* (kcal). The term *calorie* is commonly used in place of kilocalorie. One calorie is equal to 4.184 kilojoules (kjoules) a common unit of energy used in the physical sciences and internationally in nutrition labeling. The caloric intake that is appropriate for an individual depends on a number of factors, including height, weight, gender, and age.

2. Calorie Contribution of Macronutrients

Attention to caloric intake is a key element of weight control (the other is caloric expenditure). The three macronutrients that provide energy in our diets are carbohydrate, protein, and fat (see text box on Carbohydrates and Other Macronutrient Contributions to Caloric Value at Appendix B). (Alcohol is also a source of energy, yielding 7 calories per gram, but it is not a nutrient.[7]) These macronutrients yield different amounts of energy in the form of calories per unit weight.

- Carbohydrate = 4 calories per gram
- Protein = 4 calories per gram
- Fat = 9 calories per gram

To maintain a constant bodyweight over time, "energy in" from food must equal "energy out" as a result of resting metabolism plus physical activity. In other words, calories eaten should equal the calories expended on a daily basis. Bodyweight will change if one alters this basic balance. If one consumes even slightly more calories than one expends over time, one will eventually gain weight (Wright, *et al.*, 2004). Conversely, if one consumes fewer calories than one expends over time, one will eventually lose weight.

B. FDA's Public Health Mission and Legal Authorities

FDA's mission is to promote and protect the public health. It seeks to accomplish this mission by enforcing the laws it is charged with administering and by conducting educational and public information programs relating to its responsibilities.

The Federal Food, Drug, and Cosmetic Act (the Act) as amended by the Nutrition Labeling and Education Act of 1990 (NLEA, Public Law 101-535), together with FDA's implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of the total daily diet. The statute and the regulations were also intended to provide incentives to food manufacturers to improve the nutritional quality of their products.

The cornerstone of the NLEA is the Nutrition Facts panel (NFP), which lists the total number of calories derived from any source, as well as the total number of calories derived from total fat. The amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein in the food are also listed in the NFP, both as the quantitative "amount per serving" (grams or milligrams) and, with the exception of sugars and protein, as the percent of a dietary reference value, called the "percent Daily Value" (%DV). FDA requires the declaration of nutrients as a %DV, in part to help consumers understand the role of individual foods in the context of the total daily diet. Also, to help consumers determine how their individual dietary needs compare with the reference daily values used on the label, the NFP includes a footnote that specifies that the reference daily values are based on a 2,000 calorie diet. On larger packages, the footnote goes on to list the daily values for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for both a 2,000 and a 2,500 calorie diet.

As part of FDA's regulations implementing the NLEA, the agency established reference amounts customarily consumed (RACCs) for 139 food categories that manufacturers are to use in developing serving sizes that are then expressed in household measures (e.g., teaspoons, cups, pieces). These serving sizes become the basis for reporting the amount of each nutrient present and enable consumers to compare the nutritional qualities of similar food products.

Under the NLEA, FDA also has authority over health claims and nutrient content claims for foods. Appropriate health claims and nutrient content claims, like nutrition labeling, further the statutory objectives of enabling consumers to make more informed and healthier food product choices and encouraging manufacturers to improve the nutritional quality of their products.

A health claim is a claim that characterizes the relationship between a food, or a food component, and a disease or a health-related condition, and may only be made in accordance with an authorizing regulation issued by FDA. An example of a health claim is: "Although many factors affect heart disease; diets low in saturated fat and cholesterol may reduce the risk of heart disease." A nutrient content claim is a claim that characterizes the level of a nutrient in a food, and it, too, must be made in accordance with an authorizing regulation issued by the agency. Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as "free," "high," and "low," or they compare the level of a nutrient in a food to that of another food, using terms such as "more," "reduced," and "lite." More information on FDA's implementation of these authorities can be found at http://www.cfsan.fda.gov/~dms/hclaims.html.

Restaurants, unlike the manufacturers of packaged foods, are not required by the NLEA to provide nutrition information for a menu item or meal unless a nutrient content claim or a health claim is made for such item or meal. When such a claim is made, the restaurant need only provide information on the amount of the nutrient that is the basis of the claim. Thus, for example, if a restaurant claims that a particular menu item is "low in fat" (i.e., makes a nutrient content claim with regard to fat) then this requirement is satisfied by adding: "low fat - provides fewer than 3 grams fat per serving" (i.e., the basis of the "low fat" claim). The restaurant may provide information about the nutrient for which the claim is made in various ways, including in brochures. In other words, restaurants need not provide such information on the menu or menu board.

A restaurant making such a claim also would not be required to provide complete nutrition information; its decision to provide nutrient content information about one nutrient does not

trigger a requirement to disclose complete nutrition information for that item or meal.

C. Stakeholder Participation

From the outset, FDA asked stakeholders to identify obesity issues that FDA should address. Prior to the creation of the OWG, DHHS convened a round table discussion in late July 2003 (bringing together experts from academia, the health professions, industry, and government) to consider how best to address the obesity issue, as reflected in five questions presented to the round table for discussion (see Appendix C for the five questions). As noted above, DHHS also established a Docket in FDA (Docket No. 2003N-0338) to gather information on this subject.

Following the creation of the OWG, FDA provided several opportunities for stakeholder participation: a public meeting on October 23, 2003; a workshop on November 20, 2003, that was co-sponsored and funded by the DHHS Office of the Assistant Secretary for Planning and Evaluation (OASPE); roundtable meetings with health professionals/academicians and consumer groups respectively, on December 15 and 16, 2003; and meetings with representatives of the packaged food and restaurant industries. FDA used these opportunities to solicit public comments on the obesity issue, as reflected in six questions the agency asked (these questions are set out in section VI.A. of this report). FDA used the Docket established in July 2003 (Docket No. 2003N-0338) to gather additional comments; the OWG organized the comments to this docket into a searchable database that informed preparation of this report.

D. The OWG's Work

The remainder of this report reflects the work of the OWG subgroups:

- ***Obesity Knowledge Base:*** Gathered information on existing obesity, weight management, and nutrition related programs.
- ***Messages:*** Identified existing obesity-related messages in the public and private sectors; conducted focus groups to test five messages; recommended a calorie focus for FDA's action plan.
- ***Education:*** Explored and is initiating a number of new and enhanced private and public sector partnerships to focus on obesity education.
- ***Food Label:*** Explored options for enhancing the food label in relation to efforts to address obesity.
- ***Restaurants/Industry:*** Explored options for providing consumers with nutrition information on food consumed outside the home; considered the potential health consequences of using diet plans and related products.
- ***Therapeutics:*** Surveyed existing therapies for mitigating obesity; recommended next steps for updating the 1996 draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs."
- ***Research:*** Identified gaps in obesity knowledge and areas for further biomedical and social sciences research.
- ***Stakeholder Investment:*** Held meetings and a workshop to solicit stakeholder views; and organized the comments to Docket No. 2003N-0338 into a searchable database that informed preparation of this report.

III. Messages

The Commissioner charged the OWG to set out specific means for developing and implementing a "clear, coherent, and effective FDA message (within the broader context of DHHS) that will unify various public and private efforts to reverse the current obesity epidemic." This part of the charge was expanded with an eye toward establishing a broader theme that focuses on calories[8] as a fulcrum for further action, in the context of an overall healthful diet as defined by the DHHS/USDA *Dietary Guidelines for Americans.*

A. Obesity Knowledge Base

Prior to considering obesity messages and to ensure that it was aware of the range of current public and private efforts to address obesity, the OWG formed a subgroup to collect information on existing and planned obesity-related activities in the United States; assemble a centralized repository of the information gathered; and report out to the full OWG on the scope/contents of the repository.

A majority of the activities listed in the repository and database are programs that provide advice on nutrition/diet and/or physical activity. Most associations, agencies, and organizations identified are sending out the message that diet and physical activity should be addressed together in the fight against obesity.

Many partnerships or collaborations exist between government agencies and/or private entities. There are several areas, however, where different groups manage similar programs. These similar programs, if merged into a larger partnership, could have a greater impact.

To determine whether various programs, activities and initiatives are effective in reducing and/or preventing overweight and obesity in the United States, program evaluation must improve. In addition, improvements are needed in educational outreach to convey the messages and implement the initiatives that government and non-government entities have developed.

B. Obesity Messages

Message Recommendation Highlight:

- ***Develop messages tied to a "calories count" focus***

The OWG formed a subgroup to identify existing messages in the public and private sectors and to set out specific means for developing simple, clear, coherent, and effective FDA messages around the theme of "calories count" based on the scientific fact that net calorie gain or loss over time is the root cause of obesity.

1. Identifying Existing Messages

Today, consumers are inundated with a range of messages about food. Some of these messages are in the form of food advertisements or marketing efforts that focus on product convenience,

taste and value. Other messages relate to weight-loss programs or products, or weight management. Some of the messages in each of these areas may not necessarily direct consumers toward wise dietary choices.

The Federal government tries to provide long-term sound nutrition advice to consumers (e.g., government-sponsored public health campaigns). For example, DHHS collaborates with the USDA to establish and promote the *Dietary Guidelines for Americans,* which provide guidance on choosing a lifestyle that combines sensible eating with regular physical activity. An important recent effort of DHHS is *Steps to a HealthierUS.*[9] In support of the President's *HealthierUS*[10] initiative, the DHHS effort emphasizes personal responsibility for the choices Americans make to ensure that policy makers support prevention programs that foster healthy behaviors.

2. FDA Focus Groups on Obesity Messages

Box 2 - FDA Focus Groups

FDA conducts its own consumer research to evaluate the appropriateness and effectiveness of its messages. For example, FDA conducted consumer research before the implementation of NLEA, to determine the usefulness of potential choices for the NFP format. Since NLEA, FDA and other researchers have studied how consumers use the NFP, nutrient content claims, and health claims (separately and in combination) to make dietary choices.

Consumer research is used to assess people's knowledge, attitudes, perceptions, and preferences for a topical subject area or reactions to any type of stimuli. Research methods may include qualitative studies, such as focus groups; quantitative, nationally representative surveys, using structured questionnaires; experimental studies of consumer responses to labeling and package variations; and intervention studies of the effects of point of purchase labeling.

In November-December 2003, FDA, with OASPE funding, conducted focus group research. There were 8 groups of 7-10 participants. Groups were segregated by gender and education level. All participants were at least 18 years old, had been grocery shopping and had eaten in a fast food and/or quickservice restaurant in the past month. The purpose of the groups was to explore (1) how consumers use the nutrition information on food labels; (2) what type of nutrition information they would like to see in quickservice restaurants; and (3) which messages would be effective as part of a public information and education effort aimed toward encouraging consumers to use the food label. Participants discussed and reacted to variations in the NFP and the principal display panel (PDP) on food packages and to various presentations

of nutrition information at restaurants.

It is important to emphasize that the findings from these focus groups are based on qualitative research with small sample sizes. They should not be viewed as nationally representative or projectable. Quantitative experimental data are necessary to make reliable and verifiable conclusions. However, these focus group results shed some interesting light on the complex issues discussed in this report and are useful in identifying quantitative research needs.

The focus group findings discussed in this report are preliminary and are based on observations recorded by the observer, as well as post-group discussions with the focus group moderator and other observers.

In November and December 2003, FDA focus groups were convened to evaluate, among other things: (1) how consumers use the nutrition information on food labels; and (2) which messages would be effective as part of a public information and education effort aimed toward encouraging consumers to use the food label (see Appendix G for FDA Division of Market Studies report, referenced in this report as FDA, 2003).[11] Appendix H contains a discussion on the development of effective consumer messages. The findings from the FDA focus group efforts are discussed below.

FDA developed five NFP-based messages that the agency tested through its focus groups. The messages and materials were intended to remind people where to find the NFP, why it is there, and how to use the information; while at the same time reinforcing various "promises" (i.e., motivators) associated with regularly using the NFP.

The messages tested were as follows:

1. "Read it before you eat it - Always look at the Nutrition Facts"
2. "Calories count and fat matters - Always look at the Nutrition Facts"
3. "Do you know the serving size? - Always look at the Nutrition Facts"
4. "What you eat is what you are - Always look at the Nutrition Facts"
5. "If you read labels for things you put *on* your body, why wouldn't you read labels for what you put *in* your body?"

Overall, none of these "slogan-type" messages resonated particularly well with the FDA focus group participants. Nevertheless, FDA focus group participants believed that reminder messaging about the NFP would be helpful. In addition, the results of other focus groups indicate that messaging should emphasize small, incremental steps versus major life changes with respect to weight management and obesity prevention, and should address the importance of "planning ahead" as a necessary step for eating right (Borra *et al.*, 2003; IFIC, 2003).

C. OWG Message Recommendations

The OWG recognizes that some focus group (Borra *et al.*, 2003; FDA, 2003; IFIC, 2003) and some quantitative data (Derby and Levy, 2000; Levy, 2004; Lin, 2004) indicate that not all consumers pay enough attention to calorie information in the NFP. Nevertheless, given the fact that obesity, at its most fundamental level, is a direct function of caloric imbalance, the OWG believes that "calories count" must be the focus for its recommendations. Accordingly, in relation to messages, the OWG recommends the development and testing of messages tied to this focus.

IV. Education Program to Deliver the Message

Education Recommendation Highlight:

- ***Establish partnerships to educate Americans about obesity and leading healthier lives through better nutrition.***

The Commissioner directed the OWG to outline an FDA program (component of DHHS program) for educating Americans about obesity and the means to prevent chronic diseases associated with it.

A. Need for Education Programs

Consumer perceptions regarding weight and dietary habits are significant in the fight against the obesity epidemic. Consumers who are not aware of their own weight status and its medical implications are unlikely to be receptive to public health efforts to alleviate obesity. This point extends to parental perceptions of children's weight status and dietary habits as well, given that parents have significant influence over their children's environment, habits, and health. Lack of knowledge about weight status and its health implications undermine consumers' "promise" or motivation, a key component of messaging; therefore the OWG identified education as a critical adjunct to effective messaging about caloric balance.

Recent focus group studies conducted by the International Food Information Council (IFIC)[12] suggest that consumers distinguish between "overweight" and "obesity," and consider the first to be of relatively little health significance (IFIC, 2003). Therefore, consumers who consider themselves to be merely "overweight" may have less incentive to take action. There is also evidence to suggest that both adults (Kuchler and Variyam, 2003) and teenagers (Kant, 2002) misperceive their weight status, although the form of misperception can vary with gender, socioeconomic status, age and race and ethnicity. For example, men were found to be more likely than women to underestimate the level of their weight status; healthy or underweight women were more likely to consider themselves overweight. Lower income and education were also associated with underassessment of weight status; higher income and education levels were linked to overestimation of weight status. Parents also appear prone to misjudge their children's weight status and its health significance (Borra *et al.*, 2003; Contento *et al.*, 2003; Maynard *et al.*, 2003). Many parents with overweight children consider their children to be at a healthy weight. In some cases this may be due to cultural perceptions of appropriate weight (Bruss *et*

al., 2003; Contento *et al.*, 2003). In some cases where parents do accurately judge their children's weight status, they may believe that the child will outgrow their overweight or obese status and, therefore, be less likely to take action.

Consumers may have difficulty accurately assessing the nutritional quality of their diet. Although consumers report in focus group studies that they understand what comprises a healthy diet (IFIC, 2003), approximately 40 percent of one sample (almost 3000 household meal preparers drawn from USDA 1994-1996 Continuing Survey of Food Intakes by Individuals (CSFII) data) perceived the quality of their diets to be better than the calculated diet quality (Variyam *et al.*, 2001). Parents, in particular, do not always have a clear picture of their children's diets. In a recent series of focus groups and phone/Internet surveys conducted by the American Dietetic Association Foundation (Moag-Stahlberg *et al.*, 2003), parents significantly underestimated the frequency with which children ate outside of regular mealtimes, such as after dinner and while engaged in sedentary activities like television viewing. A recent report by the Kaiser Family Foundation discusses the role of media in childhood obesity (KFF, 2004).

Qualitative research by Borra and colleagues (Borra *et al.*, 2003) also suggests that children (aged 8-12 years) give little thought to good health, although they associate achieving "good health" with what they eat, rather than with physical activity. For many of the children involved in the research by Borra and colleagues, the term "healthy" had negative connotations; for example, it meant having to eat fruits and vegetables they did not like or not eating their favorite foods. In terms of weight, children between 8 and 10, regardless of their own weight, did not think about food choices. Equally disturbing, some 11-12 year olds who were overweight said they tried to lose weight by skipping meals, rather than by eating differently. Among a group of children perceived to be above normal weight for their age, Borra and colleagues found that although the children knew it was important to eat healthfully because their parents stressed it at home and they learned about nutrition in school, this teaching provided little useful information for the children.

These qualitative findings are supported by a recent unpublished survey conducted for the nonprofit Dole Nutrition Institute of more than 6,000 children between grades 1-8 in 194 classrooms (Dole, 2003). The responses to survey questions "What is obesity?" and "Which statement is true [about being overweight]?" indicate that many children seem to have either misperceptions or are misinformed about (1) the meaning of obesity and (2) the value of exercise in preventing or mitigating health problems due to overweight.

B. OWG Education Recommendations

The OWG recommends that FDA focus its education strategy on influencing behavior, as well as imparting knowledge, in the context of healthy choices for consumers. Any such efforts will require a long-term agency commitment. Education programs should help consumers make more informed food choices that result in better weight management; should direct messages to large audiences on a frequent basis; and should be crafted to reach a variety of audiences.

The OWG recommends that FDA implement education programs incrementally and design them to be flexible enough to take into account new research findings and policy decisions and possible changes in the food label (e.g., revisions to the content or format of the NFP). Education efforts, however, should not be delayed pending such changes. Education programs

should be simple to understand and apply, and should focus on showing consumers how to achieve a specific goal.

Given the resources and time that FDA would need to develop and implement new education programs for multiple subpopulations, the OWG recommends that FDA, as part of a larger DHHS initiative, establish relationships with private and public sector partners for educational outreach. Such efforts will have the ability to reach larger and more diverse audiences on a more frequent basis, and will enable calorie-focused education campaigns to begin more quickly. Given the prevalence of obesity among children, establishing relationships with youth oriented organizations is especially important. For this reason, the following partnerships are being pursued as a part of a larger DHHS initiative:

- **Girl Scouts of the USA :** FDA and Girl Scouts of the USA seek to launch an initiative entitled "Healthy Living." Building on current Girl Scout resources and programs, the initiative will provide girls and their families with the skills, knowledge, and support needed to make healthier food choices, engage in physical activity, build self-esteem, and maintain a healthier lifestyle. This initiative includes developing a charm of the food label as a part of the Studio B teen collection.
- **National Association of State Universities and Land Grant Colleges (4-H program):** Youth health and obesity is one of three strategic priorities for 4-H Youth Development. FDA envisions a partnership that will use 4-H for targeted population evaluation of obesity/nutrition message(s), and use the 4-H network of over 3,500 professional Cooperative Extension programs across the United States for education and delivery of the message(s).

In addition, FDA, along with other components of DHHS, is participating in the "Shaping America's Youth" initiative to identify actions being taken to address childhood and adolescent inactivity and excess weight. Information collected for this initiative in an on-line survey will be used by "Shaping America's Youth" to prepare a report that provides an overview of current public and private programs that target physical activity and nutrition in our nation's children. As of the date of this report, Shaping America's Youth has registered over 1950 programs directed at the childhood obesity issue, collected surveys of funding and tactical information from over 1150 organizations and entities, and assembled nearly 800 fully completed in-depth surveys from programs representing all 50 states and the District of Columbia.

Public sector partnerships should have the goal of developing programs similar to the "Power of Choice" program FDA developed with the USDA, which teaches children who are 11-13 years of age how to make smart food and physical activity choices in real-life settings. Learning how to use the NFP to make healthy food decisions is a major skill throughout the "Power of Choice" program (see Appendix I for additional information about "Power of Choice"). One way to help better ensure collaboration and cooperation with our public health partners is for FDA to coordinate its messages and educational material with those of its partners.

- **Centers for Disease Control and Prevention:** FDA is pursuing a collaboration between the agency and the CDC to develop a holistic approach to healthy living for children that will enable the FDA to meld a caloric intake message with a CDC caloric output message on physical activity.
- **Department of Education:** FDA has made preliminary contact with the Department of Education to join in supporting programs that target school-age children.

- **Department of Agriculture:** FDA plans to work through DHHS with counterparts at USDA to ensure that the agency's focus on calories is considered as USDA revises its Food Stamp Program/WIC (Women, Infants, and Children) programs and its Food Guide Pyramid, and as DHHS and USDA collectively revise the *Dietary Guidelines for Americans.*

The OWG recommends that FDA work through a facilitator to establish a forum for stakeholders to seek consensus-based solutions to specific aspects of the obesity epidemic in the United States, with a particular focus on the needs of children. As a first step, the OWG further recommends that the initiation of such a dialogue be raised at the next meeting of the FDA Science Board.

V. Supporting the Message

It is important to support any message(s) through appropriate actions and policies where the "calories count" focus is likely to have an impact on consumer knowledge, behavior, and/or treatment (i.e., food labels, restaurants, therapeutics, and research).

A. Food Labels

Food Labeling Recommendation Highlights:

- ***Calories:***
  - ***Issue an ANPRM to solicit public comment on how to give more prominence to calories on the food label.***
  - ***Consider authorizing a health claim on "reduced" or "low" calorie foods.***
  - ***Issue an ANPRM about serving sizes.***
- ***Serving Sizes:***
  - ***Encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes and label as a single-serving those food packages where the entire contents can reasonably be consumed at a single-eating occasion.***
  - ***Highlight enforcement of serving sizes in FDA's food labeling compliance program and consider enforcement action against products that declare inaccurate serving sizes.***
- ***Carbohydrates:***
  - ***File petitions and publish a proposed rule to provide for nutrient content claims related to carbohydrate content of foods, including guidance for use of the term "net" in relation to the carbohydrate content of foods.***
- ***Comparative Labeling Statements:***
  - ***Encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to***

> ***make healthy substitutions, including calories (e.g., "instead of cherry pie, try our delicious low fat cherry yogurt - 29 percent fewer calories and 86 percent less fat").***

The Commissioner directed the OWG to "develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity."

1. The Food Label

The Act, as amended by the NLEA, and FDA's implementing regulations require an NFP on the label of most packaged foods. The NFP lists the serving size, the number of servings per container, the number of calories per serving and the amount and %DV[13] per serving for specified nutrients.

Before recommending any changes in the NFP relevant to obesity, it is important to understand how consumers currently use the NFP and to assess whether the NFP has been effective in facilitating positive dietary change. Research shows that most consumers are familiar with the nutrition information on food labels (Marietta *et al.*, 1999; Neuhouser *et al.*, 1999; Kristal *et al.*, 2001; FDA, 2003), which they use primarily for evaluating the nutrition quality of specific food products, but the percentage of consumers who use NFP information productively for weight management purposes is low (Barone *et al.*, 1996; FMI, 1996; Ford *et al.*, 1996; Levy *et al.*, 1996; Mitra *et al.*, 1999; Roe *et al.*, 1999; Garretson and Burton, 2000; Levy *et al.*, 2000; IOM, 2003; FDA, 2003) (e.g., see Table 1 below).

Table 1. Recent Trends in Reported Food Label Use: 1994-2002 HDS Surveys (Derby and Levy, 2000; Levy, 2004; Lin, 2004)

	1994	**1995**	**2002**
Sample size (N)	**(1,945)**	**(1,001)**	**(2,743)**
	% population (weighted)	**% population (weighted)**	**% population (weighted)**
(1) Percent who use food labels "often" or "sometimes" when buying a food product for the first time			
How often do you read the food label?	70	69	69
(2) Percent who use labels "often" for specific purposes[1]			
To figure out how much to eat	34	40	35
To see if food is high or low in calories, salt, vitamins, fat, etc.	77	83	67

To help in meal planning	34	36	32
(3) Percent who use specific label information "often"[2]			
Do you use the serving size information, when available?	29	26	Not Asked

[1] Based only on label users who "often" or "sometimes" use labels when they buy a food product for the first time.

[2]Based on all respondents.

Associations between dietary behavior and food label use have also been identified, although the body of literature is relatively small (IOM, 2003). A low-fat diet, for example, has been positively correlated with food label use, both in the general population and among family clinic patients. Clinic patients with health conditions (e.g., high blood pressure or high cholesterol) as well as consumers who are in action or maintenance stages of dietary change were also more likely to use the food label (Kreuter *et al.*, 1997; Marietta *et al.*, 1999; Neuhouser *et al.*, 1999; Kristal *et al.*, 2001). In addition, label claims (e.g., low sodium and low fat) may allow consumers to avoid specific ingredients or make food substitutions (Balasubramanian and Cole, 2002), resulting in changes to dietary patterns. Kim and coworkers (Kim *et al.*, 2001) analyzed data from the USDA's CSFII and the Diet and Health Knowledge Survey. Their findings indicate that food label use is positively correlated with measurable increases in the Healthy Eating Index (Kim *et al.*, 2001).[(14)]

Despite reports of a positive correlation between label use and certain positive dietary characteristics, the trend toward obesity has accelerated over the past decade. It may be that consumers do not take advantage of the available information on the food label to control their weight, perhaps because they do not appreciate how the information could be used for weight management purposes or perhaps because they find it too hard to apply the available information to such purposes. In any case, it is clear that consumers would benefit if they were to pay more attention to and make better use of information, including calories, on food labels. Providing encouragement and making it as easy as possible for consumers to do so are worthy public health objectives.

2. FDA Focus Groups on Food Labels

As described in Box 2, FDA recently conducted focus group research in which it asked general nutrition questions as well as how consumers use the nutrition information on food labels.

The questions covered under general nutrition dealt with three topics: (1) attitudes towards nutrition; (2) macronutrients; and (3) %DV. Those covered under food label modification dealt with six topics: (1) large package sizes; (2) serving versus package; (3) calorie-related variations; (4) serving size variations; (5) calorie cues; and (6) "healthier" symbol. For additional information on FDA's focus group findings, see Appendix G.

Attitudes towards nutrition. In many of the groups, especially the women's groups, participants cared about nutrition and report using the NFP. At the same time, however, many also said that

they do not always consider nutrition when deciding what to eat. Taste, convenience, price, what kind of mood they are in, and what their family eats were often at odds with healthy eating. Although participants were interested in calories, many pointed to multiple concerns that went beyond calories such as the level of saturated fat, total fat, cholesterol, carbohydrates and sodium. Many participants reported not wanting to spend a lot of time reading labels.

Macronutrients. In general, individual participants tended to care more about some macronutrients than others, depending on their individual dietary practices. In most groups, at least one participant was familiar with the Atkins diet and many of these participants were most concerned about carbohydrates and sugars. Others were concerned about fat and saturated fat. Some participants checked the NFP mostly for information about sodium. Those who were on the Weight Watchers diet were concerned about calories and fiber.

%DV. Very few participants reported using the %DV column on the NFP. Either they did not understand the meaning of %DV or they thought that it was not relevant to them since they did not consume a 2000 calorie diet. Those who did use or might use %DV thought that is was a good way to estimate how much of a particular nutrient they were eating or to gauge a healthy and balanced diet.

Large package sizes. In all the groups, participants were presented with a mock-up label of a 20 ounce soda and a large packaged muffin. Both of these products are thought to be commonly consumed in one sitting, but have more than one serving listed.

Serving versus package. In general, participants thought it was misleading to list either product as having more than one serving. Many participants did realize that if the entire package is eaten, the number of servings should be multiplied by the amount of the nutrient of interest, though some participants were confused and made mistakes when trying to calculate the total amount in their heads.

Calorie-related variations. The first test label added a %DV for calories, removed the *calories from fat* line, enlarged the calories line, and changed the way serving size was declared. In general these changes were not noticed by participants. When the new wording for serving size was pointed out, most participants did not think it was an improvement over the existing language.

Serving size variations. The second test label had two %DV columns on the NFP, one for a specified serving size and one for the entire package. In the first four groups, the absolute quantities of macronutrients were only listed for the specified serving size. After comments from these groups, the label was modified to have the absolute amount for both the specified serving size and the entire product. Participants reacted positively to this modification, but some thought it was not necessary to list the amount for a specified serving size.

Calorie cues. Both a "starburst" with the calories per serving and a white square with calories per whole product on the package's PDP were tested. Many participants thought that the starburst was misleading because they thought the manufacturer was trying to indicate the entire product had fewer calories than it did. The white square with the total calories per product got mixed reactions, but many participants just said that they recognized these as high calorie products and would stay away from them.

"Healthier" symbol. Half of the groups tested a "healthy" meat lasagna with a purple keyhole symbol on the PDP. There was generally positive reaction to including a front-of-package symbol indicating that a product was "healthy," as long as participants understood the definition of the symbol and could trust that it was true. Participants believed that they would have to be educated as to the meaning of such a symbol. Some participants mentioned that they would look for the symbol when they were in a hurry in the store. They expressed some concern that these products would cost more or that they would lack in taste.

3. OWG Food Label Recommendations

The OWG recommends that FDA (1) develop options for revising or adding caloric and other nutritional information on food packaging (examples provided below); (2) obtain information on the effectiveness of these options in affecting consumer understanding and behavior relevant to caloric intake; and (3) evaluate this information to make evidence-based decisions on which option(s) to pursue.

a. Calories and Serving Sizes

In light of the critical importance of caloric balance in relation to overweight and obesity, the OWG recommends that FDA: (1) solicit comment on how to give more prominence to calories on the food label; (2) consider authorizing a health claim on "reduced" or "low" calorie foods; and (3) reexamine the agency's regulations about serving size.

Solicit comments on how to give more prominence to calories on the food label. Many of the written and public comments submitted to the agency suggested that FDA develop ways to emphasize calories on the food label. To address this, the OWG recommends that FDA publish an ANPRM requesting comments on how best to give more prominence to calories. Possible changes to the NFP include: (1) increasing the font size for calories; (2) providing for a %DV for calories; (3) eliminating "calories from fat" listing as this takes the emphasis away from "total calories;" and (4) increasing the font size for serving size in order to give it more prominence.

Consider authorizing a health claim on "reduced" or "low" calorie foods. A number of comments submitted to the agency, including those from the FTC, suggested that FDA permit health claims on reduced calorie foods as a way to reduce the risk of certain chronic diseases associated with obesity, such as diabetes, coronary heart disease and cancer. To address this suggestion, the OWG recommends that FDA publish an ANPRM on whether to allow a health claim such as "Diets low in calories may reduce the risk of obesity, which is associated with diabetes, heart disease, and certain cancers" on certain foods that meet FDA's definition of "reduced" or "low" calorie. In addition, the OWG recommends that FDA encourage manufacturers to use dietary guidance statements (e.g., "to manage your weight, balance the calories you eat with your physical activity; have a carrot, not the carrot cake; and as a snack have an apple rather than a serving of potato chips").

Reexamine the agency's regulations on serving sizes. The comments that FDA has received at its public meetings and to the docket (including comments from the FTC) express concern about the serving sizes used in nutrition labeling, particularly on packaged products that can readily be consumed at one occasion but that indicate they represent more than one serving. To

address this issue, the OWG recommends the following:

- In the short-term, that FDA encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes (21 CFR 101.9(b)(6)) that allows food packages to be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.
- In the long-term, that FDA develop two separate ANPRMs. The first would solicit comment on whether to require additional columns within the nutrition label to list the quantitative amounts and %DV of the entire package on those products and package sizes that can reasonably be consumed at one eating occasion or, alternatively, declare the whole package as a single serving. This ANPRM would also solicit information on products and package sizes that can reasonably be consumed at one eating occasion. The second ANPRM would solicit comments on which, if any, RACCs of food categories appear to have changed the most over the past decade and therefore need to be updated.

The serving size is critical to nutrition labeling since all of the information on nutrient levels depends on the amount of the product represented. By statute, the serving size is to be based on the "amount [of the food] customarily consumed" (section 403 of the Act). Accordingly, when implementing NLEA, FDA reviewed food consumption data obtained from USDA's 1977-78 and 1987-88 Nationwide Food Consumption Surveys and, based on the results of that review, established RACCs for 139 food categories (58 FR 2229, January 6, 1993). Inasmuch as there is evidence that Americans are eating larger portions than they did in the 1970s and 1980s, the OWG recommends that FDA determine whether and, if so, how to update RACCs.

The accuracy of the information in the NFP is crucial for consumers who use this information to monitor their intake of calories and nutrients. Current enforcement efforts targeted at the NFP as described in FDA's Food Labeling Compliance Program[15] are directed at ensuring that actual nutrient levels are within 20% of declared values. More limited resources have been directed at ensuring that serving sizes are calculated and declared accurately. Comments and other information submitted to FDA express concern about the inaccuracy of serving size declarations used in nutrition labeling and reiterate the importance of accurate serving size declarations because all of the information on nutrient levels is dependent upon the amount of the product represented. To address this issue, the OWG recommends that FDA highlight enforcement of serving sizes in the Food Labeling Compliance Program by April 2004, and consider enforcement activities against those products that declare inaccurate serving sizes.

b. Carbohydrate[16] Labeling

Today there is increasing interest in low carbohydrate diets (see text box on Carbohydrates and Other Macronutrient Contributions to Caloric Value in Appendix B). FDA has recently received petitions requesting that the agency provide for nutrient content claims related to the carbohydrate content of foods. Claims for carbohydrate content of foods have become increasingly common in the marketplace while, at the same time, the level of carbohydrates in foods marketed under the various carbohydrate claims appears to vary widely. In order to ensure that terms are consistently defined and that carbohydrate claims are not false or misleading, the OWG recommends that FDA file these petitions and publish a proposed rule to provide for nutrient content claims related to the carbohydrate content of foods, including guidance for the use of the term "net" in relation to carbohydrate content of foods.

c. Other Labeling Issues

The OWG considered comments from the FTC on the issues of (1) reduced/fewer calorie comparisons, (2) comparison to food of different portion size, (3) comparison to food of different product type, and (4) disclosure requirements for comparative claims.

Reduced/fewer calorie comparisons. The underlying principle for FDA's regulation is that reductions be **significant** compared to the reference food (21 CFR 101.60(b)(4). FDA determined that percentage reductions less than 25% were too small to be meaningful because of normal product variability. Such variability may be caused by factors such as: natural nutrient variability of the food due to season of the year, soil type, variety, and weather conditions; variability in processing; rounding rules (e.g., rounding to the nearest 5 calories up to 50 calories and to the nearest 10 calories above 50 calories); analytical variance (ranging from +/- 3-4% to +/- 30 % with an average variance of about +/- 15%); sampling procedures; and shelf life and stability of nutrients in the product.

As a result, 21 CFR 101.9(g) allows for a 20% excess in the actual (analytical) nutrient content of calories, sugars, total fat, saturated fat, cholesterol or sodium of a product compared to the declared nutrient values for that product (and consequently the qualifying values for nutrient content claims) before the food is considered to be misbranded. Therefore, nutrient reductions less than 25% are virtually within the allowable product variability and are not considered significant. The minimum absolute reduction (e.g., equivalent to the value of "low") was changed to permit claims compared to reference foods that were not already "low" in the nutrient because it was the agency's conclusion that benefits derived from several servings of nutritionally modified nutrient dense foods over a day could have a significant impact provided that the reduction was significant, i.e., 25 % or more. FDA further concluded foods already "low" in that nutrient were below the level at which the amount of nutrient in the food becomes significant relative to the total diet and therefore should not be used as reference foods.

For relative claims, the OWG notes that the Codex Alimentarius Commission[17] requires that there be a difference of at least 25% in energy value or nutrient content (except for micronutrients where a 10% difference in the nutrient reference value would be acceptable) with a minimum difference between the compared foods equivalent to a "low" value (FDA's proposed requirements for "less"). Moreover, Canada requires that comparative claims be based on differences which are both nutritionally and analytically significant.[18] Canadian regulations consider reductions of less than 25% from the reference value to be of questionable nutritional significance. Canada does not allow claims on reductions of less than 25%.

The OWG recommends the agency be receptive to such a claim, if the proponent of such a claim is able to provide data and information to substantiate that:

1. The claim is not misleading due to the known variations in food composition and analytical methods, and
2. The claimed reductions are nutritionally significant.

Comparison to food of different portion size. FTC has suggested that FDA consider "allowing food marketers to make truthful non-misleading label claims comparing foods of different portion sizes." FTC provided the example of a 10 oz chicken and rice casserole labeled as

having 33 percent fewer calories than 15 oz. of the same chicken and rice casserole.

Consuming a smaller portion size of the same food simply decreases caloric consumption proportionally. To enable consumers to make meaningful comparisons for calorie reduction, FDA requires such claims to be based on the amount per RACCs, or per 100 gram in the case of meal-type products. Thus, under FDA's current regulations (21 CFR 101.60(b)), a comparative calorie claim of the type that FTC proposes would not be allowed.

Nevertheless, using the food label to promote consumption of smaller portions may have merit. This is especially true if consumers understand that (a) the calorie reduction is solely a function of the reduction in portion size, and (b) that the smaller portion size is actually less than what they usually consume. Thus, the OWG recommends that FDA issue an ANPRM to solicit comments on truthful non-misleading and useful approaches for promoting consumption of smaller portion sizes, including FTC's suggestion.

Comparison to food of different product type (which the OWG refers to as comparative labeling statements). FTC suggests that FDA "consider allowing food companies to make label claims that compare the calories of foods [across] different product categories." FTC points out that switching from one category to another category often can be an effective means of reducing calories, such as substituting carrot sticks for potato chips or fruit for cookies. FTC notes that comparative caloric claims across categories could help consumers make these healthy substitutions. FTC offered as an example, "instead of cherry pie, try our delicious low fat cherry yogurt - 29 percent fewer calories and 86 percent less fat."[19]

Current FDA regulations do in fact permit certain comparative claims. In addition to the example that FTC provided, the OWG offers the following as examples of comparative claims that are permissible under current regulations:

- One medium apple (80 calories) contains 47% fewer calories than a one ounce serving of potato chips (150 calories).
- Carrots have 93% fewer calories than carrot cake. One 7-inch carrot (78 g) contains 35 calories while one slice of carrot cake with icing (125 g) contains 500 calories.
- Air-popped popcorn (without added toppings) contains one-half the calories of a plain granola bar (98 calories per 3-cup serving of popcorn, 200 calories per 1.5 ounce granola bar).

The OWG recommends that FDA encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions, including calories. Such comparisons provide valuable information that can be used in making food choices. Moreover, there is a flexible standard for product categories that is intended to facilitate useful comparisons for foods that are generally interchangeable in the diet (for example, "apples have less fat than potato chips") while prohibiting meaningless or misleading claims (58 FR 2302 at 2363, January 6, 1993). Manufacturers have to use judgment in developing claims to ensure that the claims comply with the regulations and are not false or misleading under section 403(a) of the Act.

Disclosure requirements for comparative claims. FTC suggests that FDA "evaluate whether unnecessarily cumbersome disclosure requirements have deterred truthful, non-misleading

comparative label claims for foods." As always, FDA is open to dialogue on such an issue, particularly when a proposal is supported by relevant data and information.

To make a comparative nutrient claim, a food marketer must provide information on the reference food, the percentage by which the nutrient in the reference food has been changed, and the absolute amount of the nutrient in the labeled and reference food (21 CFR 101.13(j)(2)). The agency, however, is not wholly prescriptive as to the actual words used or where all the information is placed on the label.

FTC offered as an example, a baked potato chip that is lower in both calories and fat than a regular potato chip, and indicated that label claims explaining the benefits would be awkward to place (and read) on the front panel. According to FTC, under FDA regulations, the claim would read as follows (italicized phrases may be placed on the back nutrition label):

> "Reduced fat and fewer calories than our Classic Potato Chips. Fat reduced by 85 percent, *from 10 grams per ounce to 1.5 grams per ounce*. Calories reduced by 27 percent, *from 150 calories per ounce to 110 calories per ounce*."

The OWG notes that the FTC example could be more succinct. As FTC suggests, more than 50% of the text may be placed on the back nutrition label. Beyond that, under FDA's current regulations (21 CFR 101.13(j)), the PDP could simply read:

> 85% less fat and 27% fewer calories than our Classic Potato Chips.

B. Restaurants/Industry

Restaurants/Industry Recommendation Highlights:

- ***Short-term***
  - ***Urge restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for consumers.***
  - ***Encourage consumers routinely to request nutrition information in restaurants***
- ***Long-term***
  - ***Development of a series of options for providing voluntary, standardized, simple, and understandable nutrition information, including calorie information, at the point-of-sale to consumers in restaurants.***
    - ***FDA to seek participating restaurants for a pilot program to study these options in well controlled studies***
    - ***FDA to provide incentives, if necessary, for voluntary industry participation in the pilot program.***
    - ***FDA to evaluate results of the pilot program to***

determine whether further research is warranted before such a program is implemented on a large scale.

- ***Exploration of the concept of third-party certification of weight-loss diet plans and related products.***

- ***Enforcement***
  - ***Together with the FTC, increase enforcement against weight loss products having false or misleading claims.***

The Commissioner directed the OWG to "develop an approach for working with the restaurant industry to create an environment conducive to better informed consumers."

In light of the growing proportion of American meals consumed outside of the home, it is important to enlist the assistance and support of restaurants in addressing population obesity. Since the late 1990s and projecting through 2004, American households are spending approximately 46 percent of their total food budget on food consumed outside the home (ERS, 2003; NRA 2004). During 1994-1996, food consumed outside the home, especially from restaurants and quickservice food establishments, contributed 32 percent of daily intakes of energy calories, 32 percent of added sugars, and 37 percent of fat (ERS, 2000). Thus, food consumed away-from-home is an important part of American diets and more informed dietary choices away-from-home could help reduce calorie over-consumption and the risk of obesity and its associated health problems.

The distribution of meal sources has also shifted over the past few decades, and this shift may be another significant factor in weight gain. Food consumed outside the home has increased from approximately 33 percent of U.S. consumers' food budget in 1970 to approximately 47 percent as of 2002 (ERS, 2003; Young and Nestle, 2002). Over a similar period, total calories from food consumed outside the home, especially from quickservice restaurants, increased from 18 percent to 32 percent. In addition, food consumed outside the home was higher per meal in calories, total fat and saturated fat, as well as was lower in fiber, calcium and iron on a per-calorie basis (Guthrie *et al.*, 2002).

As noted above, under the laws administered by FDA, restaurants are not required to provide nutrition information unless a nutrient content or health claim is made for a food or meal. When claims are made, however, the restaurant need only provide information about the amount of the nutrient that is the subject of the claim. Restaurants may, and many do, provide nutrition information on a voluntary basis. Nevertheless, this nutrition information is often in the form of posters, placemats or menu icons, or on the Internet; rather than at the point-of-sale. Such information is not always readily available or observable at the point-of-sale.

1. FDA Focus Groups on Restaurants

As described in Box 2, FDA recently conducted focus group research in which it asked questions about what type of nutrition information participants would like to see in quickservice restaurants. Participants discussed and reacted to various presentations of nutrition information at restaurants. The questions dealt with four topics: (1) nutrition information; (2) menu board

information; (3) menu board section; and (4) "healthier" symbol. For additional information on FDA's focus groups, see Appendix G.

Nutrition information. Most participants seemed interested in having nutrition information available to them when they eat at fast food and/or quickservice restaurants, though they might not use it every time they eat out. Participants suggested that this information could be presented in many locations in the restaurant including food wrappers, tray liners, brochures, on the take-away bags, posters near the counter, and the menu boards.

Menu board information. Participants reacted to multiple versions of a menu board for a typical fast food restaurant. In general, participants liked having calories listed after meal items and after combo meals. Those who tend to order *a la carte* preferred to have calories listed after each item, while those who usually order a combo meal preferred to have calories listed for the entire meal. Although participants were concerned with multiple macronutrients for foods, having just calories listed was enough for many of them. Participants thought that calories could be a signal for the level of other macronutrients.

Menu board section. Most participants also reacted favorably to the idea of placing healthier options, including meals, in a separate section of the menu board so they could find healthier options at a quick glance.

"Healthier" symbol. Many participants also reacted favorably to a purple keyhole symbol for healthier meals, but some thought that the exact number of calories should be listed as well. Again, the symbol would have to be trusted and consumers would have to understand the meaning of the definition.

2. OWG Restaurant Recommendations

The OWG recommends that FDA encourage restaurants to provide more, and more readily available, nutrient content information at the point-of-sale. The restaurant industry has voiced concern that requiring nutrition labeling for all menu items is infeasible because recipes change frequently, and patrons often request customization of their meals and the number of options available for customization is large. For example, recent National Restaurant Association research indicates that 70% of consumers customize their meals when eating in restaurants.[20] Nevertheless, the OWG believes that the restaurant industry could provide some level of nutrition information to its patrons to enhance their ability to make wise food choices. Calculating nutrition information may have been a difficult task for most members of this industry in the past, when such information had to be determined by direct chemical analysis. This task, however, is easier today because nutrient composition databases and software for labeling are readily available. Possibilities for providing nutrition information to consumers include: segregating "healthier" menu items with simple nutrition information in a separate section of the menu; providing icons for individual "healthier" menu items; and presenting nutrition information in locations in the restaurant where patrons can readily use it (i.e., at the point-of-sale).

The OWG also recommends that FDA encourage consumers routinely to request nutrition information in restaurants. Because restaurants respond to consumer demand (as evidenced by comments made by members of the restaurant panel at the November 20, 2003, workshop),

such demand may help create an impetus for more restaurants to provide such information.

The OWG believes that there is a need for research to determine the best way(s) to present nutrient content information to consumers so that they will make healthier choices when eating food away from home. The OWG recognizes, however, that such research will take a substantial period to plan and complete. In the interim, the pervasiveness of the obesity epidemic means that more nutrition information must be presented to consumers in restaurant settings. Accordingly, the OWG has developed both short-term and long-term recommendations

The OWG recommends that in the short-term, FDA urge the restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for customers.

Over the long-term, the OWG recommends that:

> *(1) Options be developed for providing voluntary standardized, simple, and understandable nutritional information, including calorie information, at the point-of-sale in a restaurant setting.*

Ideally these options should focus on the caloric content and nutritional composition of complete meals rather than individual menu items. Although a focus on total calories is the most useful single piece of information in relation to managing weight, additional information on nutrient content of the meal is also important. This is true, for example, for people with diabetes or coronary heart disease who need to more carefully control their consumption of certain nutrients (e.g., carbohydrates, sodium, fat). An alternative to listing detailed numeric information is to use a graphical representation that conveys the same information using a picture or symbol.

> *(2) FDA seek participating restaurants for a pilot program to study these options in well controlled studies.*

The number of restaurants participating in the pilot program should be large enough to include a variety of locations, cuisines, and average price of menu items. The pilot program needs to be long enough to account for any time required to understand the new menu formats and nutrition information. Participating restaurants would need to provide item-by-item sales data before, during, and after the pilot. Experimental economics methods could substitute partly but not wholly for actual market data to assess the impact of various labeling options on consumer behavior.

FDA could also use this pilot program to explore engaging the restaurant industry as a powerful distribution system for the agency's messages on obesity and its education programs.

> *(3) FDA provide incentives, if necessary, for voluntary industry participation in the pilot program.*

Such incentives could include allowing restaurants to use FDA's name to promote the pilot in advertising, on stickers, and on their menus; and/or coupling the pilot program with an overall FDA education campaign, which may include space on restaurant menus or on separate handouts for FDA messages on healthy lifestyles.

(4) FDA evaluate results of the pilot program.

FDA would need to analyze the results of any pilot program to determine whether further research is warranted before such a program is implemented on a large scale.

In order to pursue these more long-term recommendations, the OWG recommends that FDA work through a facilitator to provide a forum for stakeholders to seek consensus-based solutions to specific aspects of the obesity epidemic in the United States, with a particular focus on food consumed away from home. As a first step, the OWG further recommends that the initiation of such a dialogue be raised at the next meeting of the FDA Science Board.

3. OWG Weight-Loss Diet Plan Recommendations

Just as consumers spend a significant amount of money for foods consumed outside the home, they spend substantial sums on weight-loss diet plans and diet-related products. Such plans and products have the potential to affect all food choices by at least some consumers. The long-term weight or health effects of these and other weight control measures remains unclear (Connors and Melcher, 1993; Ayyad and Andersen, 2000; Saris, 2001; Anderson, *et al.*, 2001; and Phelan, *et al.*, 2003). This raises the question of whether consumers who follow these plans and buy these products understand the health implications, particularly the systematic difficulties of long-term weight management. For these reasons, the OWG also considered the health consequences of using weight-loss diet plans and related products. The OWG concluded that, in the long-term, research needs to be done outside of FDA to determine whether claims for such diet plans and related products have been or can be substantiated. Thus, the OWG recommends that there be an exploration of the concept of third party certification of weight-loss diet plans and related products. The goal is to improve consumer information about the health consequences of their overall dietary choices.

With respect to diet-related products, on December 18, 2002, FDA announced a significant enforcement initiative targeted at misleading claims about dietary supplement-associated health benefits. Dietary supplements are used by an estimated 158 million Americans, and so misleading claims about their health benefits may have significant consequences - not only for wasting consumers' money but also for luring consumers interested in improving their health in wrong directions. Although FDA's enforcement goals related to truthful and non-misleading statements about health benefits apply to all of the products the agency regulates, this initiative was especially focused on products that in recent years have been the subject of important misrepresentation.

As part of the December 18 announcement, FDA released the "Dietary Supplement Enforcement Report" that pledged to closely scrutinize and bring enforcement actions against products identified as "clearly problematic." Dietary supplements that falsely claim effectiveness as treatments for overweight were included among those identified as "clearly problematic."

CFSAN and the Office of Regulatory Affairs have focused their dietary supplement enforcement budgets principally on targeted inspections and, where appropriate, recommending enforcement action against parties who violate the Dietary Supplement Health and Education Act (DSHEA). In terms of the strategies used to enforce DSHEA, FDA has proceeded on

several fronts: (1) traditional enforcement activities (e.g., inspections, warning letters, seizures and injunctions, criminal enforcement); (2) inter-agency and international enforcement; and (3) consumer and industry education.

More recently, in December 2003, FTC staff released a report, *Deception in Weight-loss Advertising Workshop: Seizing Opportunities and Building partnerships to Stop Weight-Loss Fraud* (FTC, 2003). This FTC staff report lays out a number of opportunities for industry and media to assume a leadership role in addressing deceptive weight loss advertising. To complement these efforts, the OWG recommends that FDA continue its enforcement initiative targeted at misleading claims about dietary supplement weight loss products.

C. Therapeutics

Therapeutics Recommendation Highlights:

- ***Convene an FDA advisory committee meeting to address challenges, as well as gaps in knowledge, about existing drug therapies for the treatment of obesity.***
- ***Continue discussions with pharmaceutical and medical device sponsors about development of new obesity therapies.***
- ***Revise 1996 draft guidance on developing obesity drugs and re-issue for comment.***

The Commissioner directed the OWG to "develop an approach for facilitating the development of therapeutics for the treatment of obesity."

The role of obesity in many acute and chronic diseases is well documented. The contribution of obesity to premature mortality through increased risks of diabetes, heart disease, stroke, and cancer, among others, mandates an aggressive, proactive stance by the entire medical community.

1. Background

Modern medicine's experience with weight loss drugs dates to the late nineteenth century when initial enthusiasm for the weight loss properties of thyroid extract were eventually tempered by the negative effects that iatrogenic hyperthyroidism had on lean muscle mass, bone, the central nervous system (CNS), and cardiac function (Schwartz, 1986; Bray, 1976). The next century of obesity drug development saw the introduction of a number of drugs that proved to have significant side effects: Dinitrophenol (cataracts, neuropathy) in 1934; Amphetamine (addiction, CNS and cardiac toxicity) in 1937; Rainbow pills, or digitalis and diuretics (cardiac arrest) in 1967; Aminorex (pulmonary hypertension) in 1971; and Redux (cardiac valvulopathy) in 1996 (Bray and Greenway, 1999).

Prior to 1996, all approved obesity drugs were labeled for short-term treatment of obesity based on pre-approval clinical trials of up to 12 weeks' duration and of limited size by today's standards. Over the past 10-15 years, increasing recognition of several facts have led to changes

in the approach to the treatment of obesity and thus to the study of new drugs for this condition: (1) obesity is a chronic condition with long-term morbid and mortal sequelae; (2) maintenance of weight loss, even while on continued drug therapy (and certainly after discontinuation of drugs) is the rare exception rather than the rule; and (3) maintenance of a "healthy" weight (rather than weight "cycling") is the key to reduced risk for obesity-associated adverse sequelae.

2. FDA's Draft Guidance

In 1996, FDA issued draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs." The draft guidance gives recommendations for the design and conduct of phase 1-3 clinical studies aimed at demonstrating the effectiveness and safety of weight-loss medications.[21] This guidance proposed two alternative criteria for effectiveness for drug therapies:

- Mean weight loss in the drug-treated group is 5% greater than the mean weight loss in the placebo group following one year of treatment.
- The proportion of patients that lose at least 5% of their baseline weight is greater in the drug vs. the placebo group.

3. Existing Therapies

Under the criteria in the 1996 draft guidance, three drugs have been approved for the long-term treatment of obesity: dexfenfluramine (Redux) in 1996 (withdrawn in 1997 for safety reasons), sibutramine (Meridia) in 1997, and orlistat (Xenical) in 1999. In addition, a number of drugs were approved prior to 1996 for the short-term (e.g., a few weeks) treatment of obesity (e.g., phentermine (Adipex) and diethylpropion (Tenuate)).

FDA-approved drugs for the long and short-term treatment of obesity are indicated for use by those patients with: (1) a body mass index of > 27 kg/m^2 when accompanied by obesity-related comorbidities such as hypertension, diabetes, and dyslipidmeia; or (2) a body mass index > 30 kg/m^2.

For patients with extreme obesity (those with BMIs at or over 40), for whom no other measures have been effective in promoting weight loss, surgical or device-mediated gastroplasty is increasingly employed. Worldwide, over 100,000 of these devices have been implanted over the past 8 years. In the United States alone, tens of thousands of devices are implanted each year to restrict the size of the stomach and thus severely limit food intake. Despite serious complications, gastroplasty procedures as well as device implantations are effective for some individuals, with average durable loss of 35-40% of excess (over ideal) weight.

4. OWG Therapeutics Recommendations

Ideally, individual consumers will avoid becoming overweight or obese through diet and exercise. Yet the OWG recognizes that obese and extremely obese individuals are likely to need medical intervention to reduce weight and mitigate associated diseases and other adverse health effects. The OWG concurs with agency plans to (1) convene an FDA advisory committee meeting to address challenges, as well as gaps in knowledge, about existing therapies (i.e., head-to-head comparisons of marketed drugs, cardiovascular endpoint studies); (2) continue

discussion with pharmaceutical and medical device sponsors about new obesity medical products; and (3) revise 1996 draft guidance on developing obesity drugs and re-issue for comment.

D. Research

Research Recommendation Highlights:

- ***Pursue research on obesity prevention with USDA/ARS.***
- ***Support and collaborate, as appropriate, on obesity-related research with others, including NIH***
- ***Pursue obesity related research in the following five areas:***
  - ***Information used to facilitate consumers' weight management decisions.***
  - ***Relationship between overweight/obesity and food patterns.***
  - ***Incentives to product reformulation***
  - ***Potential for FDA regulated products unintentionally to contribute to or result in obesity***
  - ***Translational research conducted by the National Center for Toxicological Research (NCTR) and CFSAN's Office of Applied Research and Safety Assessment (OARSA)***

The Commissioner directed the OWG to "identify applied and basic research needs relative to obesity that include the development of healthier foods as well as a better understanding of consumer behavior and motivation."

1. Joint Research with USDA/ARS

As part of its research efforts, the OWG recommends that FDA collaborate with USDA/ARS on a national obesity prevention conference to be held in October 2004. The conference will draw on the expertise of both the public and private sector scientific communities to provide guidance for research agendas in the short- and long-term to address obesity prevention from a variety of scientific and other disciplines. Such disciplines will include diet and nutrition, behavioral and economic science, and research involving exercise, education, integrated programs, and outreach.

2. Survey of Research

The OWG focused on three areas of research related to its charge: (1) "labeling information"[22] and consumer perceptions and dietary behaviors with regard to weight management; and (2) support for safety evaluation with respect to the potential for FDA regulated products unintentionally to contribute to or result in obesity; and (3) translational research conducted by FDA's National Center for Toxicological Research and CFSAN's Office of Applied Research

and Safety Assessment. to enable the agency to use the basic scientific research conducted by such agencies as the NIH in FDA's regulatory activities. Of these three, the OWG considers the first two to be more directly and immediately relevant to its charge. Translational research, because of its link to basic nature, takes a long time to yield practical results. Nevertheless, the OWG believes FDA should continue to conduct translational research in order to gain a better understanding of obesity.

Based on a review of the relevant research as well as comments provided during a variety of public meetings, the OWG has identified several knowledge gaps related to the two research areas above. The OWG recommends that further obesity-related research be conducted in the following areas: (1) information used to facilitate consumers' weight management decisions, (2) the relationship between overweight/obesity and food consumption patterns, (3) incentives to product reformulation, and (4) the potential for FDA-regulated products unintentionally to contribute to or result in obesity, and (5) the extension of basic research findings to the regulatory environment through translational research. In addition, the OWG recommends that FDA pursue collaborations with other groups who are undertaking obesity research such as NIH, which has recently issued an obesity research agenda, and CDC.

Information used to facilitate consumers' weight management decisions. The OWG recommends conducting additional qualitative and quantitative research with an emphasis on (1) consumer reaction to and effectiveness of current packaged food labeling and possible changes to the food label (e.g., highlighting calories, listing the quantitative amounts for all nutrients in multi-size packages, and using "healthy" symbols, graphic devices, or caloric/nutrient density indicators), (2) consumer reaction to and effectiveness of current restaurant nutrition information and possible changes (e.g., listing nutritional information such as calories, fat and sodium for both *a la carte* items and meals and using "healthy" symbols), and (3) consumer dietary behavior and attitudes toward weight management.

Relationship between obesity and food consumption patterns. The OWG recommends conducting research to evaluate the relationship between obesity in adults and children and the frequency of foods obtained from and/or consumed in different locations (e.g., home cooked meals, packaged foods, and quickservice establishments/restaurants) and with respect to socioeconomic status and vulnerable populations (e.g., Hispanic Americans, African Americans, American Indians, and the elderly). This research would be conducted in collaboration with the Economic Research Service of the USDA using CDC and National Health and Nutrition Education Survey data to evaluate these relationships.

Incentives to product reformulation. The OWG recommends conducting further research with the packaged food and restaurant industries in addition to that currently being conducted by OASPE in collaboration with FDA (FDA, 2003). This research would (1) examine whether the incentives (e.g., label prominence and other label characteristics of calorie and weight management information) and barriers (e.g., food additive and claims approval processes and the regulatory policy related to standards of identity and fortification) to reformulation identified by the packaged food industry during previous discussions are real or perceived, and (2) expand the scope of the research conducted by OASPE to include additional discussions with key restaurant industry, including quickservice, personnel regarding the barriers and incentives to the development/reformulation of healthier restaurant foods.

Potential for FDA-regulated products to unintentionally contribute to or result in obesity.

Although most FDA-regulated products are intended to be used or consumed for purposes other than weight management, weight gain may be an unintentional adverse side effect associated with use of some of these products. In general, for both foods and drugs, weight gain or obesity has not consistently been measured, evaluated, or considered as an adverse effect when designing study protocols or evaluating submitted research results. Strategies to systematically evaluate this endpoint are needed as part of the safety assessment for FDA-regulated foods and drugs. Thus, the OWG recommends conducting research to investigate (1) the promotion of weight gain as an adverse side effect of FDA-regulated drugs and whether this is a factor that should be taken into account regarding drug safety and (2) the development of animal model assessment strategies that encompass the evaluation of long-term effects on weight gain as a safety assessment parameter.

Translational research. Translational research is essential for FDA to use basic research from other agencies and academic institutions in developing regulatory policies and actions. Thus, the OWG recommends extending basic research on (1) developmental imprinting[23] to differentiate among food components and eating behaviors of neonates, or nutrient/food component exposures of fetuses via maternal diets, with regard to weight management challenges in adolescence and adulthood, (2) biomarker and effects-evaluation techniques through emerging genomics, proteomics and metabolomics technologies to identify how FDA-regulated products modify risk factors and susceptibilities for weight gain, obesity, and co-morbidities, and (3) development of animal models to evaluate the effects of diets and dietary components, drug therapies, and medical device uses on long-term weight maintenance, health and longevity. The OWG further recommends that FDA take into account translational as well as other obesity-related research being done by NIH, as it considers future research in these areas.

VI. Stakeholder Investment to Help Ensure Results

Stakeholder Investment Recommendation Highlight:

- ***Continue to promote and engage in active dialogue with invested stakeholders.***

The Commissioner charged the OWG to set out specific means for developing and implementing "an active dialogue with outside invested stakeholders including consumers groups, academia, and the food and restaurant industry on developing a framework for consumers to receive messages about reducing obesity and achieving better nutrition."

A. Background

Recognizing the high level of interest in obesity among FDA's many stakeholders, the OWG initiated a process for establishing ongoing relationships with individuals and organizations from all sectors. A key aspect of this process included providing the public with multiple opportunities to become involved in a dialogue with the OWG on its activities and the issues associated with helping consumers address the problem of obesity.

As one of its first major outreach initiatives, the OWG sponsored a public meeting on October 23, 2003,[24] to accomplish several objectives:

- To initiate a discussion of FDA's role and responsibilities in addressing the major public health problem of obesity;
- To focus on issues related to promoting better consumer dietary and lifestyle choices that have the potential to significantly improve the health and well-being of Americans; and
- To obtain stakeholder views on how best to build a framework for messages to consumers about reducing obesity and achieving better nutrition.

Approximately 320 attendees representing diverse stakeholder viewpoints registered to participate in this discussion, with nineteen organizations making formal presentations on issues associated with the six focus questions. These nineteen organizations represented science/research, academia, consumers, health and medical associations, industry, and advocacy groups. In addition to the formal presentations given at the October 23 public meeting, interested and concerned stakeholders submitted written comments to Docket No. 2003N-0338 on various aspects of the six focus questions.

The scope of the discussion at this meeting, and at two subsequent roundtable meetings (held with health professionals/academicians and with consumer groups, on December 15-16, 2003, respectively) centered on the following six focus questions:

1. What is the available evidence on the effectiveness of various education campaigns to reduce obesity?

Stakeholders regarded education as an essential component of FDA's contribution to public health efforts to confront the problem of obesity. Stakeholders consistently reinforced FDA's leadership role in educating the public about the food label, good nutrition, and healthy diets.

Stakeholder comments focused on four key areas: (a) effectiveness of existing education campaigns; (b) type of education campaigns needed; (c) what campaigns should address; and (d) what messages are likely to affect weight gain, weight management, or weight loss.

2. What are the top priorities for nutrition research to reduce obesity in children?

Stakeholders were particularly concerned about childhood obesity. Stakeholders emphasized the importance of parental involvement in efforts to address childhood obesity. The views focused on the scope of the problem, as well as on the research on activities that are needed to address the issue of childhood obesity.

3. What is the available evidence that FDA can look to in order to guide rational, effective public efforts to prevent and treat obesity by behavioral or medical interventions, or combinations or both?

Stakeholders expressed a range of views and perspectives about what would inform FDA decisions in preventing and treating obesity.

4. Are there changes needed to food labeling that could result in the development

of healthier, lower calorie foods by industry and the selection of healthier, lower calorie foods by consumers?

Stakeholders were highly interested in participating in the area of food labeling. The views focused on (a) general advice; (b) calories; (c) energy balance; (d) serving sizes; (e) current health-related information on the label; (f) consumer education on the food label; (g) messages on the food label; and (h) expanding nutrition information availability in restaurants.

5. What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?

Stakeholders provided a diverse array of research needs, creative incentives for the development of healthier foods/diets, and general advice.

6. Based on the scientific evidence available today, what are the most important things that FDA could do that would make a significant difference in efforts to address the problem of overweight and obesity?

Stakeholder views related to three major categories: (a) food labels; (b) research; and (c) education.

On November 20, 2003, FDA, in conjunction with OASPE, sponsored a workshop on "Exploring the Connections Between Weight Management and Food Labels and Packaging."[25] The two major issues explored at this workshop were:

- Current food labels and packaging: Effects on weight management and reduced risk of overweight and obesity and
- Data supporting options for change

This daylong workshop involved presentations by researchers, academicians, and public health officials, who discussed issues such as the effect of portion/package size, shape and structure on consumption (e.g., comments by Brian Wansink in transcript of November 20 workshop); and presentations by representatives of the restaurant industry, who addressed issues surrounding provision of nutrition information in restaurants.

The OWG organized the comments to Docket No. 2003N-0338 into a searchable database that informed preparation of this report.

FDA also met with representatives of the packaged food and restaurant industries to learn about their obesity-related activities.

B. OWG Stakeholder Investment Recommendations

The OWG believes it is worthwhile to maintain contacts with stakeholders concerned about the obesity issue both to benefit from their continued involvement and to ensure that, to the extent possible, collective obesity efforts are mutually supportive.

VII. Overall Conclusions

In response to the charge to the OWG, this report provides a range of recommendations for addressing the obesity epidemic. These recommendations address multiple facets of the obesity problem under FDA's purview, including developing appropriate and effective consumer messages to aid consumers in making wiser dietary choices; formulating educational strategies in the form of partnerships, to support the dissemination and understanding of these messages; specific new initiatives to improve the labeling of packaged foods with respect to caloric and other nutritional information; initiatives enlisting and involving restaurants in the effort to combat obesity; the development of new therapeutics; the design and conduct of effective research in the fight against obesity; and the continuing involvement of stakeholders in the process.

As noted previously in this report, achieving ultimate success against obesity will occur only as a result of the complementary efforts over time by many concerned sectors of our society. It is the belief and the hope of the OWG that the recommendations contained in this report, when carried out by FDA in concert with the complementary ongoing and planned efforts of other sister DHHS agencies and other agencies of government, will make a significant impact in reversing current trends.

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Notes:

(2) National Institutes of Health (NIH) clinical guidelines (http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/risk.htm#limitations) define "overweight" in adults as a body mass index (BMI) of 25.0 to 29.9, and "obesity" as a BMI of 30.0 or higher. BMI (see Text Box at Appendix B) is defined as the ratio of a person's bodyweight in kilograms divided by the square of his or her height in meters.

(3) For additional information on factors contributing to obesity see CDC webpage (http://www.cdc.gov/nccdphp/dnpa/obesity/contributing_factors.htm)

(4) In children, the BMI is expressed as percentile growth that is based on gender-and age specific growth charts.

(5) When the OWG was formed, Joseph A. Levitt was the Director of CFSAN, and the OWG vice-chair. As of January 5, 2004, Dr. Brackett became director of CFSAN, and assumed the role of vice-chair.

(6) For a further discussion of energy balance see, *Dietary Reference Intakes* - Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids Part 2, Chapter 12 Physical Activity; 12:1-39 (Institute of Medicine of the National Academies, 2002) and references cited therein.

(7) Although alcoholic beverages are not a focus of this report, there is some interest in having calorie and other nutrition information declared on the label of such beverages, as evidenced by a recent petition from the Center for Science in the Public Interest (CSPI) submitted to the Tax and Trade Bureau of the Treasury Department. In a letter dated December 17, 2003, to DHHS Secretary Thompson, CSPI requested that DHHS support the petition.

(8) As noted earlier in Section II.A.1., there is much discussion in the field of nutrition concerning the specific macronutrient source of calories, but given the charge to focus on obesity, the OWG believes that a primary focus on calories is appropriate.

(9) For more information on *Steps to a HealthierUS* see http://www.healthierus.gov/steps/index.html

(10) For more information on the *HealthierUS* Initiative see http://www.healthierus.gov/

(11) In addition, the focus groups explored what type of nutrition information they would like to see in quickservice restaurants (see section V.B.1.of this report). Participants discussed and

reacted to various presentations of nutrition information at restaurants.

(12) IFIC states that its mission is to communicate science-based information on food safety and nutrition to health and nutrition professionals, educators, journalists, government officials and others providing information to consumers. IFIC states that its purpose is to bridge the gap between science and communications by collecting and disseminating scientific information on food safety, nutrition and health and by working with an extensive roster of scientific experts and through partnerships to help translate research into understandable and useful information for opinion leaders and ultimately, consumers. IFIC is supported primarily by the food, beverage and agricultural industries.

(13) The %DV indicates the amount of a nutrient present in a serving in relation to reference levels for a daily diet. The reference levels for vitamins and minerals are based on Recommended Dietary Allowances established by the National Academies; the reference levels for macronutrients are based on recommendations in the *Dietary Guidelines for Americans* or as established by public health organizations. For macronutrients whose recommended intake levels are based on caloric intake (e.g., saturated fat intake should be less than 10% of calories), the %DV is calculated for a 2,000 calorie diet.

(14) USDA's Healthy Eating Index is a summary measure of overall diet quality. It provides a picture of the type and quantity of foods people eat and the degree to which diets comply with specific recommendations in the *Dietary Guidelines for Americans* and USDA's Food Guide Pyramid. For further information go to http://www.usda.gov/cnpp/healthyeating.html

(15) The Food Labeling Compliance Program gives instructions to FDA Field Offices that describes food labeling enforcement strategies and identifies/highlights specific areas where resources should be targeted with regard to the accuracy of the food label.(currently on the Internet at: http://www.cfsan.fda.gov/~comm/cp21008.html)

(16) For a further discussion on carbohydrates, see *Dietary Reference Intakes* - Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids Part 1, Chapter 6 Dietary Carbohydrates: Sugars and Starches 6:1-57 (Institute of Medicine of the National Academies, 2002) and references cited therein.

(17) Guidelines for Use of Nutrition Claims (CAC/GL 23-1997).

(18) Guide to Food Labeling and Advertising. Section VI. Nutrient Content Claims 6.1.9(c).

(19) This example also contains an express nutrient content claim ("try our delicious low fat yogurt"), and two relative claims ("29 percent fewer calories" and "86 percent less fat"). Hence, the statement, as written, would need to meet the regulatory requirements for these types of claims, and would also need to provide serving size information that would allow for appropriate comparison between the cherry pie and the cherry yogurt.

(20) From remarks by Hudson Riehle of the National Restaurant Association at the November 20, 2003, workshop "Exploring the Connections Between Weight Management and Food

Labels and Packaging" (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm)

(21) On January 26, 2004 (69 FR 3588), FDA issued a *Federal Register* notice specifically to solicit comments on this previously published draft guidance. FDA is interested in incorporating the latest scientific advances in the field of obesity and drug development into an amended obesity guidance document. Once the agency revises the draft, FDA will issue the guidance again for comment before finalizing the guidance.

(22) For the purposes of V.D.2., "labeling information" includes possible changes to the NFP, possible changes to the PDP, graphic devices, caloric/nutrient density indicators, and nutrient content claims.

(23) The developmental imprinting hypothesis suggests that the increase in childhood obesity is, in part, a result of an epigenetic effect of poor nutrition or exposure to some toxic agent during the perinatal period when metabolic pathways are being established in the fetus and neonate, creating a dysfunctional metabolic pathway. As the child ages, these dysfunctional metabolic pathways, in conjunction with other factors, such as inadequate exercise, may become sufficient to cause or contribute to overweight or obesity. This developmental programming hypothesis, developed from epidemiological data, has also been recently extended to animal models.

(24) In the *Federal Register* of October 8, 2003 (68 FR 58117), FDA announced this public meeting. Transcript of the meeting is available in FDA Docket No. 2003N-0338, and as of the date of this report, available on the Internet at (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm).

(25) In the *Federal Register* of October 17, 2003 (68 FR 59795), FDA announced this public workshop. On November 19, 2003 (68 FR 65303), FDA amended its original announcement to reflect that the agency was requesting comments regarding the workshop. Transcript of the workshop is available in FDA Docket No. 2003N-0338, and as of the date of this report, available on the Internet at (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm)

(26) This listing includes references in the Report and Appendices B and H

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Appendix A
List of Acronyms and Abbreviations

Table of Contents

ANPRM	Advance notice of proposed rulemaking
BMI	Body mass index
CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition
CNS	Central nervous system
CSFII	USDA 1994-1996 Continuing Survey of Food Intakes by Individuals
CSPI	Center for Science in the Public Interest
DSHEA	Dietary Supplement and Health Education Act of 1994
DHHS	U.S. Department of Health and Human Services
FDA	Food and Drug Administration
FTC	Federal Trade Commission
FR	Federal Register
IFIC	International Food Information Council
IOM	Institute of Medicine
NFP	Nutrition facts panel
NIH	National Institutes of Health
NLEA	Nutrition Labeling and Education Act of 1990
OASPE	DHHS Office of the Assistant Secretary for Planning and Evaluation
OWG	FDA□s Obesity Working Group
PDP	Principal display panel

RACCs	Reference amounts customarily consumed
the Act	Federal Food, Drug, and Cosmetic Act
USDA	U.S. Department of Agriculture
USDA/ARS	U.S. Department of Agriculture/Agricultural Research Service
%DV	Percent Daily Value
21 CFR	Title 21, Code of Federal Regulations

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Appendix B
Text Boxes on Body Mass Index (BMI), Energy (Calorie) Balance, Carbohydrates and Other Macronutrient Contributions to Caloric Value

Table of Contents

Body Mass Index (BMI)

Body mass index (BMI) is a way of characterizing weight status. For example, an adult's weight status is classified as underweight (BMI < 18.5), normal (BMI = 18.5 - 24.9), overweight (BMI = 25.0 - 29.9), or obese (BMI = 30.0). For children and adolescents, somewhat different BMI ranges are used to classify their weight status. The BMI has gained increasing use by health professionals because it is highly correlated with body fat.

The BMI values used to classify adults as underweight, normal, overweight, or obese are based on their ability to predict the effect of body weight on the risk for some diseases. For example, common conditions associated with increased risk in adults classified as being overweight or obese include premature death, cardiovascular disease, high blood pressure, osteoarthritis, some cancers, and diabetes. Although BMI is only one of many factors used to predict the risk of these diseases, it is an important factor and one that can be modified by individual changes in eating and physical activity behaviors.

For adults, BMIs are calculated from mathematical formulas that take into account an individual's height and weight. BMI can be

calculated using pounds and inches with this equation:

BMI = (weight in pounds/(height in inches x height in inches) x 703

A calculator that automatically estimates the BMI for an individual is available on the CDC Web page (http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm).

BMI values for children and teens are used to assess their body fatness changes over the years as they grow. Unlike adults, where the same BMI ranges are used for both men and women and across all ages, gender- and age-specific BMI values are used to classify the weight status of children and teens. This is necessary because children's body fat levels change over the years as they grow. Also, girls and boys differ in their body fat levels as they mature. BMI decreases during the preschool years and subsequently increases into adulthood. BMI-for-age tools are useful for children and teens because they compare well to laboratory measures of body fat levels and can be used to track body size throughout life. More information on BMI values for children is available on the CDC Web page (http://www.cdc.gov/nccdphp/dnpa/bmi/bmi-for-age.htm).

For some individuals such as athletes who have a muscular body with relatively small amounts of body fat, the use of BMI values may inappropriately classify them as overweight. For these individuals, the additional use of other estimates of body fat such as waist circumference may help to more accurately estimate their weight status. For example, a waist measurement greater than 40 inches in men and 35 inches in women is usually indicative of excessive abdominal fat, which is an independent predictor of risk factors and ailments associated with obesity.

Calorie (Energy) Balance[1]

Overweight and obesity result from an imbalance that occurs when the calories consumed exceeds the calories expended. Even small imbalances over time can result in weight changes. For example, a difference of one 12-oz soda (approximately 150 calories) or 30 minutes of brisk walking most days can add or subtract approximately 10 pounds of body weight per year.

There are many physiological factors (e.g., gut hormones) that operate to maintain body weight at a constant level even though calorie intake often varies considerably from day to day and week to